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Guidance for the Reregistration of Manufacturing-Use and Certain End-Use Pesticide Products Containing Disulfoton (032501) as the Active Ingredient

(U.S.) Environmental Protection Agency
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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

DISULFOTON
(032501)

CASE NUMBER 102

CAS 298-04-4

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product (MP) containing disulfoton as the sole active ingredient who wishes to continue to sell or distribute that product must apply for reregistration under and fulfill the requirements described in this standard.

Although the full requirements for reregistration do not apply to other products containing disulfoton at this time, registrants with such products are subject to various provisions of this standard as follows. Each registrant of a MP containing disulfoton in combination with other active ingredients is required to comply with the data requirements set forth in Table A and B of their documents, labeling revisions and reregistration are not required at this time. Each registrant of an end use product (EP) containing disulfoton as a sole active ingredient or in combination with other active ingredients are subject to the labeling and data requirements (refer to Table C) in this standard.

To carry out the task of reregistration, we have established the Registration Standards program, which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. Based on the regulatory position, the Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that registrants submit data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing use product producers (basic suppliers of the active ingredient). However, end use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	In the case of this standard that requires restrictions and labeling to protect man and the environment, these products are subject to certain provisions in this Registration Standard. Affected products are to be called in as provided for in this document.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered, that is meet the full data requirements, labeling requirements, (as appropriate) and 3(c)(1)(D) requirements imposed by this document.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. Regulatory Position

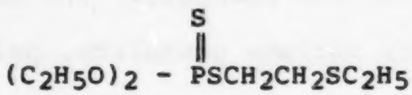
A. Introduction

This Registration Standard describes the regulatory position of the Environmental Protection Agency (EPA) on manufacturing-use products (MUP's) and certain end-use products (EUP's) containing the insecticide disulfoton as a sole active ingredient. The Agency's position is based on an evaluation of all registered uses of disulfoton and registered MUP's with disulfoton as an active ingredient.

This document provides the rationale for the Agency's position and the criteria for registration that result from it. It also discusses labeling requirements and tolerances. Finally, it considers "Special Local Needs" registrations, authorized by Section 24(c) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, in addition to federal registrations granted under Section 3 of the FIFRA. Future products that differ appreciably from those described in this Standard may require an amendment to this Standard to reflect the difference. No new uses for disulfoton will be considered until the human and environmental concerns raised in this Standard are satisfactorily resolved.

B. Chemical Description and Use Profile

Disulfoton is the common name for O, O-diethyl S-[2-(ethylthio) ethyl] phosphorodithioate. Trade names and other names include ethylthiodemeton, Disyston, dithiodemeton, dithiosystox, and thiodemeton. The chemical is manufactured in the U. S. by Mobay Chemical Corp. The empirical formula is $C_8H_{19}O_2PS_3$ and the molecular weight is 274.4. The structural formula is as follows:



$$(C_2H_5O)_2 - \overset{\overset{S}{\|}}{P}SCH_2CH_2SC_2H_5$$

The 95% technical material also serves as a manufacturing-use product under the trade name Di-Syston.

Technical disulfoton is a pale yellow liquid which hydrolyzes under alkaline conditions, with a boiling point of 62°C at 0.01 mm/Hg. It is soluble in most organic solvents and is soluble in water at 25 parts per million (ppm) at 20°C. Other physical and chemical properties are vapor pressure 1.8×10^{-4} millibars at 20°C, and specific gravity 1.144 at 20°C/4°C. Existing data gaps relating to product chemistry are identified in Table A and Table B.

There are five manufacturing-use products, 70 federally registered Section 3 end-use products, 41 24(c) Special Local

Need registrations, and 34 intrastate products containing disulfoton as the sole active ingredient. There are also a number of products containing disulfoton in combination with other active ingredients. These multiple active ingredient products include one multiple active ingredient manufacturing-use product containing disulfoton, 29 federally registered Section 3 end-use products, four 24(c) Special Local Need registrations, and 11 intrastate products. The formulation types of the above products include granulars, pelleted/tableted, emulsifiable concentrates, and ready-to-use liquids.

Disulfoton is formulated in various percentages in combination with benefin, chlorobenzilate, demeton, diazinon, dicofol, ethoprop, fensulfothion, PCNB, etridiazole, trifluralin, and vernolate.

Disulfoton, a plant systemic organophosphate chemical, is principally used as an insecticide/acaricide for the agricultural crops cotton, sorghum, and wheat. Additional registered uses include the agricultural crops alfalfa, corn, peanuts, soybeans, tobacco, pecans, various seed crops, certain fruits and vegetables, ornamentals and nursery stock, forest uses, greenhouse uses, and potted house plants.

Most granular disulfoton products are applied as pre-plant or at-planting soil treatments, although emulsifiable concentrates and ready-to-use liquids can be applied either aerially or by ground equipment. Certain formulations containing 10% or greater concentrations of disulfoton are already classified for Restricted Use (44 CFR 45131 Aug., 1, 1979) based on dermal and/or inhalation toxicity.

C. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on disulfoton, the Agency has made the following determinations:

1. An interim farm worker reentry interval of 24 hours is necessary for disulfoton under this Standard pending receipt and evaluation of reentry studies noted in Table A.

   Rationale: The Agency is concerned about possible dermal and inhalation exposure to farm workers because of disulfoton's high acute toxicity. In order to assess this potential risk, reentry studies (dermal exposure, inhalation exposure, foliar dissipation and soil dissipation studies) and toxicity (dermal absorption) data are required to be submitted. In the absence of such data interim reentry intervals will be utilized to minimize exposure to workers entering treated fields.

2. Product integrity studies on typical end-use disulfoton granular formulations are being required to assess hazards from inhalation and dermal exposure to workers and handlers from granular formulations of disulfoton.

   Rationale: Based on present use patterns and application practices there would appear to be little likelihood of exposure to workers resulting from the handling and use of the disulfoton granular formulations. However, should the granules fracture during shipping and handling, an inhalation and dermal exposure hazard to handlers and other workers subject to prolonged exposure may occur. Therefore, product integrity studies are being required to assess this possibility. Depending on results of these studies, additional precautionary labeling and/or other protective measures, as appropriate, will be implemented. In addition, a subchronic inhalation exposure study (90-day rat) and a subchronic dermal study (21-day) may be required.

3. Disulfoton and its degradation products have potential to leach through soil and contaminate ground water; however the available data is insufficient to characterize this potential. Additional studies are being requested. These studies include hydrolysis, metabolism

and mobility studies. Once these additional studies are submitted and reviewed an environmental fate assessment on disulfoton and its metabolites and their potential for ground water contamination can be made.

Rationale: Preliminary information indicates that disulfoton has a low to intermediate mobility in soils. The mobility of its metabolites are somewhat greater. Because disulfoton is mainly applied by soil incorporation, the mobility potential is further enhanced. The half-life and leaching potential of disulfoton and its degradates are unknown; however, it is believed that the degradates may persist in the soils for a relatively long period of time.

4. The "restricted use" classification for all disulfoton emulsifiable concentrates 65%, 21% (w/ Fensulfothion 43% and greater) or 32% (w/ fensulfothion 32% and greater) and greater, and ready-to-use liquids 95% and greater, and granular formulations 10% and greater (for greenhouse use) will continue. All remaining end-use product formulations greater than 2% are hereby classified for "restricted use" on an interim basis by this Standard, pending receipt and

evaluation of additional data specified in Table C. All end-use product formulations 2% and less are not now being classified "restricted use" pending receipt of toxicity data specified in Table C.

Rationale: The emulsifiable concentrates and ready-to-use liquids, and granular formulations 10% and greater (greenhouse use) were previously restricted by regulation on August 1, 1979 (40 CFR 162.31). Classification for the EC and liquids was based upon acute dermal and acute inhalation toxicity, and for the granulars for greenhouse use was based on acute inhalation toxicity.

Though granular formulations containing greater than 2% disulfoton were previously proposed for restricted use on August 1, 1979 (44 FR 54219), the Agency never promulgated a final rule classifying these formulations. All product formulations greater than 2% are being restricted through this Standard.

All product formulations greater than 2% released for shipment after September 1, 1985 must be labeled for restricted use. All such products which are in the channels of trade after September 1, 1986 must be labeled for restricted use.

The September 1, 1985 date for products released for shipment provides time for States to certify applicators and also assures that most products used in the 1986 growing season will be classified for restricted use. Requiring all products still in the channels of trade after September 1, 1986 to be so restricted will prevent stockpiling by dealers and distributors and assure that all products greater than 2% available for the 1986 growing season are restricted.

The decision to classify some disulfoton registrations as restricted use products was based on criteria set out in §162.11(c). The principal human effects triggers for chemicals used in non-domestic settings are the Toxicity Category I criteria, i.e., acute dermal LD_{50} - 200 mg/kg; acute inhalation LC_{50} - 0.2 mg/l; acute oral LD_{50} - 50 mg/kg. The principal human effects triggers for pesticides used in domestic settings are the Toxicity II criteria. Current disulfoton end use product labels carry Toxicity Category I, II, III designations. Based on extrapolation of available acute oral toxicity data in our files non-domestic use products containing 3.38% or more disulfoton would fall in Toxicity Category I and domestic use products greater than 0.3%* in Toxicity Category II and thus would be candidates for restricted use classification. The acute toxicity data base for end-use products containing disulfoton is not adequate for the Agency to make a final determination which formulations warrant the restricted-use classification. Therefore the Agency will require products greater than 2% disulfoton to be classified for restricted use until appropriate toxicity studies and other information is received. When the acute toxicity data base is complete, the Agency will review its decision regarding the classification of registered products containing more than 2% disulfoton. (Refer to Data Table C).

The majority of current disulfoton products are registered for use on agricultural crops, commercially grown ornamentals and limited forestry uses. However, there are a number of products formulated at 2% and less for use primarily by the homeowner for vegetables, flowers and potted houseplants, which remain unclassified.

*Assumptions: A 10 kg female consumes 10g of granular material containing .03g of chemical (96% pure) and complete rapid absorption takes place. Calculated from 3.38% disulfoton.

The acute toxicology data base for disulfoton end use products is severely lacking.

The Agency has decided not to classify product formulations containing 2% or less as restricted use pending receipt and evaluation of appropriate toxicity data required under this Standard (refer to Data Table C). After receipt of this data the Agency will consider the acute toxicity categories for those products 2% or less and current label language to determine if these products warrant restricted use classification.

5. The Attwater's greater prairie chicken, Aleutian Canada Goose, the Everglades kite, Slackwater darter, woundfin, 11 freshwater mussels, longhorn beetle, delta green ground beetle, and Kern primrose sphinx moth, all endangered species, may be at risk from the use of disulfoton. The Agency has decided to adopt a generic (cluster) approach for addressing endangered species concerns associated with the uses of pesticides. This cluster labeling should be complete by the 1986 growing season; if it is not, the need for interim labeling statements will be reconsidered. No labeling statements are currently proposed pertaining to endangered species.

Rationale: The Office of Endangered Species of the United States Department of Interior, representatives of agricultural interest groups and the Agency believe the conventional labeling approach is inadequate to properly inform the users on how to protect the endangered species and at the same time use the product to the greatest benefit.

It is presently anticipated that appropriate labeling will be developed in time for the 1986 growing season for these five crops. If not, this Standard may be amended to impose interim labeling to protect endangered species which may be affected by use of disulfoton.

6. No new uses of disulfoton will be allowed until the the human dietary concerns have been resolved through receipt and analysis of pending toxicology and residue data.

   Rationale: The Agency is unable to complete a tolerance reassessment because of certain residue chemistry and toxicology data gaps, therefore the Agency cannot propose a change in present tolerances. However the provisional acceptable daily intake (PADI) has been exceeded, and because of this, no new uses for disulfoton will be allowed until the human and environmental concerns raised in this standard have been addressed. (Refer to Section G: Tolerance Reassessment.)

7. The available field and laboratory studies and reports of livestock kills corroborate the Agency's findings that disulfoton is very highly toxic to fish and highly toxic to birds and mammals. The hazard to terrestrial species can result directly from ingestion of granules or indirectly by consumption of invertebrates, vegetation, or water containing disulfoton residues. Available data are not sufficient to assess the significance of this hazard, i.e., to determine if significant population reduction will occur. Full field studies including population monitoring are required. Depending on the results of the environmental fate studies, an avian reproduction study may be required as well. Depending on the results of the requested metabolism data and the likelihood that the metabolites may be more toxic than disulfoton itself acute toxicity studies of metabolites may be required for mammalian and avian species.

For the hazard to fish, additional data are needed before the Agency can complete a full assessment of this hazard potential. Depending on the results of the environmental fate studies full field studies with population monitoring may be required. A fish early life-cycle study and an aquatic organism accumulation study may also be required depending on the result of lower tier studies and environmental fate data. After the Agency has evaluated these data, it will determine whether EPA should initiate a public interim review process by placing the chemical in Special Review.

Rationale: A total risk assessment cannot be made until gaps in the data base for aquatic and terrestrial species and environmental fate are filled. Because exposure data were insufficient to judge the level of concern for disulfoton, the most appropriate regulatory action is to move expeditiously in filling the data gaps. If, after review of these data, regulation of the chemical through the normal registration process is found to be appropriate, the Agency will update its regulatory position and rationale to reflect this conclusion and the reasoning behind it.

8. Manufacturing-use and end-use products containing disulfoton must bear revised environmental hazard statements reflecting the pesticide's toxicity to fish and wildlife (refer to Section F. "Required Labeling).

   Rationale: Based upon studies available to assess hazards to wildlife and aquatic organisms, disulfoton is characterized as very highly toxic to mammals and aquatic organisms (especially freshwater fish), moderately toxic to highly toxic to birds and moderately toxic to honey bees. Updated label precautions required under this Standard should reduce the hazard to fish and other wildlife.

9. The tank mixing of disulfoton with Phosalone for use on pecans and potatoes is prohibited. (Refer to Section F, Required Labeling, for the exact labeling statement.)

   Rationale: Laboratory potentiation studies with disulfoton and other organophosphate chemicals indicates that the acute toxicity of disulfoton, when mixed with Phosalone and fed to laboratory animals, was enhanced over sixteen times. None of the other tested chemicals potentiated disulfoton's toxicity. The Agency concludes that this potentiation may occur due to a peculiarity of the Phosalone molecule, but the exact mechanism is unknown. Since the Agency has identified only two uses, (pecans and potatoes) where these two chemicals could be used together, a label prohibition against tank mixing Phosalone and disulfoton for these uses is warranted.

10. Data to evaluate spray drift potential are needed. Those data being required include droplet size spectrum studies and field evaluation of pesticide drift (refer to Table A).

    Rationale: The Agency is concerned about potential hazards to non-target organisms (domestic animals and humans) from drift after spray applications of disulfoton. This concern is due to the very high toxicity of the chemical to all mammalian species by all routes of exposure (Toxicity Category I). Pesticide Incident Monitoring System (PIMS) incidents lend some support to this concern. Of ten incidents involving domestic animal mortality or morbidity at least three involved deaths to large numbers of horses consuming disulfoton contaminated hay. Of these three incidents one was definitely attributed to spray drift contaminating grazing areas.

11. By this Standard, the Agency is requiring the submission of applications for full registration of all intrastate products containing disulfoton by December 31, 1985. An "intrastate" product is one registered by a State before August 3, 1975, and for which a Notice of Application was filed with the Agency before October 4, 1975. Such products were assigned Accession Numbers by EPA; the latter part of this number, the product number, is greater than or equal to 3000, e.g., 1256-5779. If you have such a product containing disulfoton, you must submit an application for registration including the following information:

A. An Application for New Registration (EPA Form 8570-1);

B. A complete and accurate Confidential Statement of Formula (EPA Form 8570-4);

C. A copy of draft labeling complying with the requirements of 40 CFR 162.10 and this Standard;

D. Data required by 40 CFR Part 158 for your product; and

E. Information to show your compliance with the requirements of FIFRA sec. 3(c)(1)(D) pertaining to compensation for use of data submitted by another person. (Refer to PR Notice 84-4 for the latest information.)

Any distribution or sale of an intrastate (not federally registered) product containing disulfoton after the deadline will be considered to be in violation of FIFRA sec. 12(a)(1)(A). For those intrastate products that are issued a Federal registration, the labeling timeframes set out in section 6 of this Standard (Required Labeling) apply to the product. If you do not wish to pursue Federal registration of your intrastate product, you should request withdrawal of your Notice of Application. If you request withdrawal of your Notice, or if you fail to respond to this notification, you may not distribute or sell the intrastate product after December 31, 1985. Products already in channels of trade as of that date may continue to be distributed and sold by dealers and retailers until June 30, 1986 Any product found in channels of trade after June 30, 1986 will be considered to be in violation of FIFRA sec. 12(a)(1)(A).

Rationale: At the time that the Notice of Application was filed with the Agency, the producer of the intrastate product agreed to submit an application for full Federal registration when directed to do so by the Agency. It is EPA policy that the Agency will require the producer of an intrastate product to submit an application for federal registration if the intrastate product contains the same active ingredient and is intended for the same or a substantially similar end use as federally registered products which are subject to:

A. A notice of Rebuttable Presumption Against Registration (RPAR) or Special Review;

B. A notice under FIFRA sec. 3(c)(2)(B) requiring the submission of data in support of federal registration;

C. A regulation or notice classifying the product for restricted use under FIFRA sec. 3(d)(1)(C); or

D. A notice requiring the federal registrant to submit an application for reregistration of his product.

Under FIFRA sec. 12(a)(1)(A), it is unlawful for a person in any State to distribute or sell any pesticide which is not registered under section 3 [except as provided by section 6(a)(1)].

12. Pesticide products containing disulfoton as an active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard. Affected registrants must provide (or agree to provide additional in the case of scientific studies) data, labeling and comply with the data compensation provisions of FIFRA sec. 3(c)(1)D. Applicants for new registrations of products containing disulfoton must also comply with these same requirements.

    Rationale: Under FIFRA, the Agency cannot cancel or withhold registration simply because data are missing or inadequate (see sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time if they will affect the registration(s) of disulfoton.

D. Criteria for Registration under the Standard

To be acceptable for registration under this Standard, products must contain disulfoton as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section E of this document. The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). Registration applicants must contact the Agency for specific instructions, including updated information on data requirements and companies whose data must be cited and to whom compensation must be offered.

E. Acceptable Ranges and Limits

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain disulfoton as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and any intentionally-added inert ingredients which may be present in products.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing disulfoton, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing disulfoton may be labeled for formulation into end-use products only for the commodities listed below. The attached "EPA Index to Pesticide Chemicals" entry lists all registered uses, as well as approved maximum application rates and frequencies.

-Terrestrial, non-domestic, food uses on: alfalfa, barley, beans (dry, snap, lima), bermudagrass [seed crop (24(C)] blackeyed peas (seed crop), broccoli, Brussels sprouts, cabbage, carrots (seed crop), cauliflower, clover, coffee, corn, cotton, garlic (seed crop), hops, lettuce, oats, onion (seed crop), peanuts, peas, pecans, peppers [24(C)] pineapple, potato, radish (seed crop), rice, sorghum, soybeans, spinach, strawberries (propagating plants), sugar beets, sugarcane, tomato, turnips (seed crop), and wheat.

-Terrestrial, non-domestic, non-food uses on: non-bearing fruit trees (apple, apricot, cherry, crabapple, peach, pear, plum and prune), raspberry (nursery stock), tobacco, ornamentals (herbaceous plants, woody shrubs, trees) and forest plantings.

-Domestic outdoor use on: potted plants, ornamentals (herbaceous plants, flowers, woody shrubs, trees).

-Domestic indoor use on: potted plants, ornamentals (specified above).

-Greenhouse non-food use on: ornamentals (specified above).

F. Required Labeling

All manufacturing-use and end-use disulfoton products must bear appropriate labeling as specified in 40 CFR 162.10. This guidance document contains information on label requirements. All labeling changes must appear on all products released for shipment after September 1, 1985. All labeling changes must appear on all products in channels of trade as of September 1, 1986. In addition to the above, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for MPs must list the active ingredient as:

O,O-Diethyl S-[2-(ethylthio)ethyl] phosphorodithioate....____%

2. Use Pattern Statements

All manufacturing-use disulfoton products must state that they are intended for formulation into end-use products for the aforementioned use patterns. Labeling must specify sites, which are listed in Use Patterns, Section E.3. A limiting factor will be data that supports these use patterns. No use may be included on the label where the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern.

3. Precautionary Statements

Statements for Manufacturing-Use Products

a. Labels for manufacturing-use disulfoton products must bear statements reflecting the compound's acute human toxicity. Disulfoton is in Toxicity Category I by all routes of exposure; the required precautionary statements associated with this category are specified in 40 CFR 162.10.

b. The following revised environmental hazard statement must appear on all MP labels:

> "This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Statements for End-Use Products

a. The following "Restricted Use" statement must appear on the label of disulfoton products classified for restricted use:

"Restricted Use Pesticide -
acute human oral, dermal, and inhalation toxicity"

"For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification."

b. In the use directions for pecans and potatoes add the following prohibition:

"Do not tank mix this product with Phosalone."

c. Add the following worker reentry statement to the labeling of products with directions for use on crops.

"Do not allow reentry into treated fields within 24 hours of application unless appropriate protective clothing is worn."

d. Revise the existing environmental hazards statements to read:

"This pesticide is toxic to fish and wildlife. Do not apply directly to water or wetlands. Drift and runoff from treated areas may be hazardous to fish in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or incorporate spills.

This pesticide is toxic to bees exposed to direct application. Applications should be timed to coincide with periods of minimum bee activity, usually between late evening and early morning."

e. Pursuant to PR Notice 83-2, the general worker protection statements specified in that notice must appear on the labeling of outdoor agricultural use products which are applied to crops whose culture requires hand labor. Such products released for shipment after December 31, 1984, must meet the requirements of this PR Notice.

f. In the absence of crop rotation data, the crop rotation restriction below must be placed on all products which may be used in a situation where rotation with crops used for food or feed that are not registered with disulfoton may occur: "Do not plant any food or feed crop in rotation after a field treatment with disulfoton unless it is a registered use for disulfoton."

G. Tolerance Reassessment

U. S. tolerances ranging from 0.1 to 12.00 parts per million (ppm) have been established for the combined residues of disulfoton and its cholinesterase-inhibiting metabolites, calculated as demeton* on a variety of raw agricultural commodities (RAC) (40 CFR 180.183) and on the processed feed commodities dried sugarbeet pulp and pineapples bran at 5 ppm (21 CFR 561.160). A summary of the RAC tolerances are presented in Table II located at the end of this section and include Canadian and Codex Maximum Residue Limits. There are no Mexican tolerances for the commodities listed in Table II.

The metabolism of disulfoton in plants [0,0-diethyl S-[2-(ethylthio)ethyl]phosphorodithioate (I)] is partially understood. Disulfoton is readily absorbed and translocated by plants. Table I (at the end of this section) depicts the molecular structures of disulfoton and its known metabolites. Identified metabolites included 0,0-diethyl S-[2-(ethylsulfinyl) ethyl]phosphorodithioate (II), 0,0-diethyl S-[2-(ethylsulfonyl) ethyl]phosphorodithioate (III), 0,0-diethyl S-[2-(ethylsulfinyl)ethyl]phosphorothioate (V), 0,0-diethyl S-[2-(ethylsulfonyl)ethyl]phosphorothioate (VI), 0,0-diethyl phosphoric acid (VII), 0,0-diethyl phosphorothioate (VIII), and phosphoric acid (IX). Although not identified in the available metabolism studies, 0,0-diethyl S-[2-(ethylthio) ethyl]phosphorothioate (IV) is a metabolite expected to occur as an intermediate through oxidation; this compound is identical to the demeton thiol isomer and is likely a transient disulfoton intermediary metabolite.

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*Demeton (0,0-diethyl 0-[2-(ethylthio)ethyl] phosphorothioate is a systemic organophosphate insecticide

Data delineating the quantification of all oxidative metabolites is also required for tolerance reassessment.

The Agency is requiring studies of metabolites utilizing ruminants and poultry to determine distribution and characterization of residues in tissues, milk, and eggs as well as an animal metabolism study (preferably in the rat) to delineate the pharmokinetic and pharmacodynamic aspects of disulfoton, particularly the rate of conversion of oxidation metabolites from one to another.

Tolerances are currently expressed in terms of the combined residues of disulfoton and its cholinesterase-inhibiting metabolites calculated as demeton, which consists of a mixture of the following two isomers: 0,0-diethyl 0-[2-(ethylthio)ethyl]phosphorothioate and 0,0-diethyl S-[2-(ethylthio)ethyl]phosphorothioate. The Agency has determined that it is inappropriate to calculate residues as demeton. Instead, calculation of disulfoton residues as disulfoton sulfone (III) would be more appropriate because: (i) this compound has the greatest molecular weight of disulfoton and its metabolites (18.6% higher than demeton); (ii) it appears to be a major disulfoton residue in or on plants as a result of treatment whereas demeton thiono isomer is not expected to occur as a disulfoton metabolite; (iii) all analytical methods available involve oxidation to disulfoton sulfone and/or disulfoton 0-analog sulfone and, therefore, even if present, demeton would be oxidized to the corresponding sulfone; and (iv) the Gas Chromatographic (GC) detector response is greater to disulfoton sulfone than to disulfoton 0-analog sulfone.

Disulfoton *per se* (I) is detectable only very soon after treatment of plants. The 0-analog (IV) has not been detected in plants, presumably due to rapid oxidation of the ethylthio sulfur atom of disulfoton or the 0-analog, if formed. Disulfoton sulfone (III) and the 0-analog sulfone (VI) are expected to be the major residues at the time of harvest of treated plants whereas disulfoton sulfoxide (II) and O-analog sulfoxide (V) will generally be present in lesser quantities.

Therefore the current tolerances in 40 CFR 180.183 and 21 CFR must be redefined in terms of disulfoton sulfone.

Although plant residues were found to consist almost entirely of oxidation products, the nature and magnitude of the anticholinesterase activity of these individual metabolites were not originally considered in the establishment of existing tolerances. Available studies show certain oxidation products to be more potent cholinesterase inhibitors than the parent compound, and, considering this fact, the actual toxic burden in the diet may be greater than current calculations indicate.

The acceptable daily intake (ADI) for cholinesterase inhibition in man is usually determined on the basis of a no-observed-effect-level (NOEL) from a rat chronic feeding study using a normal 10 fold safety factor. However, since the rat chronic feeding study was unacceptable for setting the ADI, a provisional acceptable daily intake (PADI) for cholinesterase inhibition was established on the basis of a NOEL from a dog chronic feeding study using the customary 10 fold safety factor.

A PADI for disulfoton of 0.0025 mg/kg/day was established using a NOEL of 1.0 ppm (0.025 mg/kg) and the maximum permissible intake (MPI) for a 60 kg person is 0.1500 mg/day.

Toxicological studies are needed to establish acceptable metabolites. The use of a PADI of 0.0025 mg/kg/day replaces the previous ADI of 0.005 mg/kg/day and may accomodate the uncertainty surrounding greater toxicity and serve to alleviate dietary concerns in the interim between issuance of this Standard and the time the Agency receives and analyzes the metabolite data. The theoretical maximum residue contribution (TMRC) to the human diet from existing tolerances is 0.2544 mg/day (in 1.5 kg of human diet) and represents 169.59% of the PADI. However, a reassessment of the current tolerances based on actual constituents of the plant residues is necessary and additional residue data are needed to determine the nature and magnitude of human dietary exposure to disulfoton's metabolites.

Although the Agency is concerned about exceeding the PADI no regulatory action is warranted now pending receipt of metabolite toxicity and residue chemistry data with which to evaluate the magnitude of human dietary exposure to disulfoton and its metabolites. The Agency believes, for several reasons, that the public will be in no immediate danger while awaiting exposure assessment data.

The TMRC assumes that 100 percent of the crop for which a tolerance is established is treated with disulfoton. Disulfoton's major uses are cotton, sorghum, and wheat, and the estimated percentage of disulfoton's use on these crops is low. When adjustments are made for the estimated percentage of crops treated with disulfoton, The Agency assumes the ratio between residue contribution and the PADI is actually much lower than 169%.

The Agency recognizes that the statistical significance of the Food and Drug Administration's market basket survey is limited, but results from this monitoring can function as an indicator of immediate dietary exposure risks. Monitoring activity for the past several years shows that although present, disulfoton residues are consistently below established tolerances, which further alleviates the Agency's immediate concern over disulfoton's use while collecting data for a tolerance reassessment. The Agency is requesting data pertinent to the reassessment of current tolerances on an accelerated basis as indicated in Table A.

Additional residue data required to support existing tolerances for disulfoton residues in or on certain commodities are listed in Table A. The Agency is also requesting that certain additional tolerances be proposed for certain agricultural commodities and feed/food items. No new crop groupings can be established at this time because of extensive residue chemistry data gaps. Compatibility between Codex MRL's and U.S tolerances will be assessed when data specified in Table A have been submitted and evaluated. Because the Agency is concerned about the magnitude of the metabolites' toxicity and their effect on the dietary assessment for disulfoton, and considering the fact that certain food processing techniques could increase the dietary exposure through enhanced oxidation, the Agency may request post-processing residue data be submitted after the above-noted residue data have been submitted and evaluated.

Table 1. Disulfoton and its metabolites.

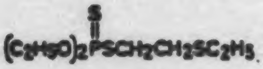
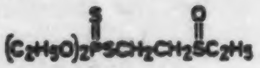
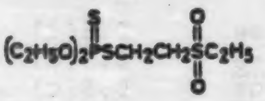
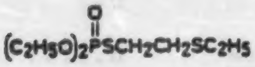
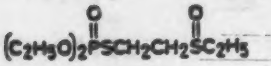
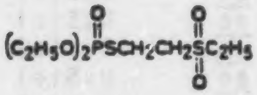
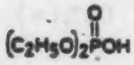
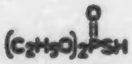
Code	Structure	Chemical Name	Abbreviation
I	 $(C_2H_5O)_2\overset{S}{\overset{\|}{P}}SCH_2CH_2SC_2H_5$	0,0-diethyl S-[2-(ethylthio)ethyl]phosphorodithioate	Disulfoton
II	 $(C_2H_5O)_2\overset{S}{\overset{\|}{P}}SCH_2CH_2\overset{O}{\overset{\|}{S}}C_2H_5$	0,0-diethyl S-[2-(ethylsulfinyl)ethyl]phosphorodithioate	Disulfoton sulfoxide
III	 $(C_2H_5O)_2\overset{S}{\overset{\|}{P}}SCH_2CH_2\underset{\underset{O}{\|}}{\overset{\overset{O}{\|}}{S}}C_2H_5$	0,0-diethyl S-[2-(ethylsulfonyl)ethyl]phosphorodithioate	Disulfoton sulfone
IV	 $(C_2H_5O)_2\overset{O}{\overset{\|}{P}}SCH_2CH_2SC_2H_5$	0,0-diethyl S-[2-(ethylthio)ethyl]phosphorothioate	Disulfoton O-analog
V	 $(C_2H_5O)_2\overset{O}{\overset{\|}{P}}SCH_2CH_2\overset{O}{\overset{\|}{S}}C_2H_5$	0,0-diethyl S-[2-(ethylsulfinyL)ethyl]phosphorothioate	Disulfoton O-analog sulfoxide
VI	 $(C_2H_5O)_2\overset{O}{\overset{\|}{P}}SCH_2CH_2\underset{\underset{O}{\|}}{\overset{\overset{O}{\|}}{S}}C_2H_5$	0,0-diethyl S-[2-(ethylsulfonyl)ethyl]phosphorothioate	Disulfoton O-analog sulfone
VII	 $(C_2H_5O)_2\overset{O}{\overset{\|}{P}}OH$	0,0-diethyl phosphoric acid	Diethyl phosphate
VIII	 $(C_2H_5O)_2\overset{O}{\overset{\|}{P}}SH$	0,0-diethyl phosphorothioate	Diethyl phosphorothioate
IX	H_3PO_4	Phosphoric acid	--

TABLE II
SUMMARY OF PRESENT TOLERANCES

	Tolerances (ppm)		
Commodity	**U.S.(a)**	**Canada**	**Codex (MRL)(b)**
alfalfa (fresh)	5.0	-	-
alfalfa (hay)	12.0	-	10.0
asparagus	0.1	-	0.5(c)
barley (fodder,green)	5.0	-	5.0(d)
barley (grain)	0.75	-	0.2(f)
barley (straw)	5.0	-	-
beans (dry)	0.75	0.5 *per se*	0.5(c)
beans (lima)	0.75	0.5 *per se*	0.5(c)
beans (snap)	0.75	0.5 *per se*	0.5(c)
beans (vines)	5.0	-	-
beets, sugar (roots)	0.5	-	0.5
beets, sugar (tops)	2.0	-	-
broccoli	0.75	0.5 *per se*	0.5(c)
brussels sprouts	0.75	0.5 *per se*	0.5(c)
cabbage	0.75	0.5 *per se*	0.5(c)
cauliflower	0.75	0.5 *per se*	0.5(c)
clover (fresh)	5.0	-	-
clover (hay)	12.0	-	10.0
coffee beans	0.3	-	0.1
corn, field (fodder)	5.0	0.1 *per se*	0.5(e)
corn, field (forage)	5.0	0.1 *per se*	0.5(e)
corn, (grain)	0.3	0.1 *per se*	0.5(e)
corn, pop	0.3	0.1 *per se*	0.5(e)
corn, pop (fodder)	5.0	0.1 *per se*	0.5(e)
corn, pop (forage)	5.0	0.1 *per se*	0.5(e)
corn, sweet (fodder)	5.0	0.1 *per se*	0.5(e)
corn, sweet (forage)	5.0	0.1 *per se*	0.5(e)
corn, sweet, grain (kernels plus cob with husks removed)	0.3	0.1 *per se*	0.5(e)
cottonseed	0.75	-	-
hops	0.5	-	-
lettuce	0.75	0.5 *per se*	0.5(c)
oats (fodder, green)	5.0	-	-
oats (grain)	0.75	-	0.2(f)
oats (straw)	5.0	-	-
peanuts	0.75	-	0.1(a)
peanuts (hay)	5.0	-	-
peanuts (hull)	0.3	-	-
peas	0.75	0.5 *per se*	0.5(c)
peas (vines)	5.0	-	-

TABLE II (cont.)
SUMMARY OF PRESENT TOLERANCES

Commodity	Tolerances (ppm) U.S.(a)	Canada	Codex (MRL)(b)
pecans	0.75	-	0.1
peppers	0.1	0.1 *per se*	0.5(c)
pineapples	0.75	-	0.1
pineapples (forage)	5.0	-	-
potatoes	0.75	0.2 *per se*	0.5
rice	0.75	-	0.5(h)
rice (straw)	5.0	-	-
sorghum (fodder)	5.0	-	5.0(d)
sorghum (forage)	5.0	-	5.0(d)
sorghum (grain)	0.75	-	0.2(f)
soybeans	0.1	-	0.1
soybeans (forage)	0.25	-	-
soybeans (hay)	0.25	-	-
spinach	0.75	0.5 *per se*	0.5(c)
sugarcane	0.3	-	-
tomatoes	0.75	0.5 *per se*	0.5(c)
wheat (fodder, green)	5.0	-	-
wheat (grain)	0.3	-	0.2(f)
wheat (straw)	5.0	-	-

Footnotes for Table II

(a) Disulfoton and its cholinesterase inhibitin metabolites, calculated as demeton

(b) Additive residues of disulfoton, demeton-S, and their sulfoxides and sulfones, expressed as disulfoton

(c) In or on vegetables

(d) In or on all green forage crops

(e) In or on maize

(f) In or on all cereal grains

(g) Kernels only

(h) In or on rice in the husk

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-2) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data1/ Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines 2/ or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

OR

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*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Test Substance[1]/	Guidelines Status[2]/	Are Data Required[3]/ Yes	No	Footnote Number
§158.120 - Product Chemistry					
Product Identity:					
61-1 - Identity of Ingredients	TGAI	R	☒	☐	
61-2 - Statement of Composition	TGAI	R	☒	☐	
61-3 - Discussion of Formation of Ingredients	TGAI	R	☒	☐	
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	TGAI	R	☒	☐	
62-2 - Certification of Limits	TGAI	R	☒	☐	
62-3 - Analytical Methods for Enforcement of Limits	TGAI	R	☒	☐	
Physical and Chemical Characteristics					
63-2 - Color	TGAI	R	☒	☐	
63-3 - Physical State	TGAI	R	☒	☐	
63-4 - Odor	TGAI	R	☒	☐	
63-5 - Melting Point	TGAI	R	☐	☒	4/

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Test Substance1/	Guidelines Status2/	Are Data Required3/ Yes	Are Data Required3/ No	Footnote Number
§158.120 - Product Chemistry (con't)					
Physical and Chemical Characteristics (Continued)					
63-6 - Boiling Point	TGAI	R	☒	☐	--
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	☒	☐	
63-8 - Solubility	TGAI or PAI	R	☒	☐	
63-9 - Vapor Pressure	PAI	R	☒	☐	
63-10 - Dissociation constant	PAI	R	☒	☐	
63-11 - Octanol/water partition coefficient	PAI	R	☒	☐	
63-12 - pH	TGAI	R	☒	☐	
63-13 - Stability	TGAI	R	☒	☐	
63-20 - Corrosion Characteristics	TGAI	R	☒	☐	
Other Requirements:					
64-1 - Submittal of samples	Choice	CR	☐	☒	

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.120 - Product Chemistry (continued)

DATA REQUIREMENT FOOTNOTES:

1/ Test Substance: TGAI= Technical grade of the active ingredient; PAI= Pure active ingredient; Choice= choice of several test substances determined on a case-by-case basis.

2/ Guideline Status: R= Required; CR= Conditionally required

3/ Data must be submitted by MAR 1985

4/ Not required because the 95% technical is a liquid at room temperature

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	GS0102001* GS0102002* GS0102003* GS0102004* GS0102005* 00032409* 00096498*	Yes[3]
- Livestock	PAIRA and plant metabolites	Partially	GS0102001* GS0102006*[a]	Yes[4][5]
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Partially	GS0102003* GS0102004* GS0102013* GS0102007* GS0102008* GS0102009* GS0102010* GS0102011*[b] GS0102012*[b] GS0102014* 00071243* 00071237*	Yes[6]

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Residue Analytical Method (continued)				
- Plant residues (continued)			00071233* 00041055*a/ 00032409* 00028780*a/	
- Animal residues	TGAI and metabolites	Partially	GS0102006*a/ GS0102007* GS0102014* 00071245*	Yes[6/]
171-4 - Storage Stability Data	PAI	Yes	GS0102002* GS0102015* GS0102006*a/ GS0102012*a/	No
171-4 - Magnitude of the Residue-				
Residue Studies for Each Food Use				
- **Root and Tuber Vegetable Group** 10/				
Potatoes	TEP	Partially	GS0102016* 00095501*a/	Yes[7/]
Sugarbeets	TEP	Partially	GS0102004* GS0102032*	Yes[8/]

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§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)			GS0102031*[a/]	
- Leaves of Root and Tuber Vegetable Group [9/]				
Sugarbeets	TEP	Yes	GS0102004* GS0102032	No
- Leafy Vegetable Group[11/]				
Lettuce	TEP	Partially	GS0102015	Yes[12/]
Spinach	TEP	Partially	GS0102017	Yes[13/]
- Brassica (cole) Leafy Vegetable Group[14/]				
Broccoli	TEP	Partially	GS0102002* GS0102018*	Yes[15/16/]
Brussel Sprouts	TEP	Partially	GS0102015	Yes[15/17/]
Cabbage	TEP	Partially	GS0102002	Yes[15/18/]
Cauliflower	TEP	Partially	GS0102015	Yes[15/19/]

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Data Requirement	Composition1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.125 Residue Chemistry (continued)				
- **Legume Vegetables (succulent or dried) Group** 20/				
Dried Beans	TEP	Yes	GS0102031*a/ GS0102015*	No
Lima Beans	TEP	Yes	GS0102031*a/ GS0102015*	No
Peas	TEP	Yes	GS0102031*a/ GS0102015*	No
Snap beans	TEP	Yes	GS0102031*a/ GS0102015*	No
Soybeans	TEP	Partially	GS0102019* GS0102011*	Yes21/
- **Foliage of Legume Vegetable Group**22/				
Bean Vines and Hay	TEP	Partially	GS0102031*a/ GS0102015*	Yes23/
Pea Vines and Hay	TEP	Partially	GS0102031*a/ GS0102015*	Yes24/

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Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.125 Residue Chemistry (continued)				
Soybean Forage and Hay	TEP	Partially	GS0102011*[b]/ GS0102019*	Yes[25]
- Fruiting Vegetables Group				
Peppers	TEP	Partially	GS0102020[b]/	Yes[26]
Tomatoes	TEP	Partially	GS0102031*[a]/ GS0102015*	Yes[27]/[28] [29]/
- Tree Nut Group[30]/				
Pecans	TEP	Yes	GS0102012*[b]/ GS0102021*	No[31]
- Cereal Grains Group				
Barley	TEP	Partially	GS0102031*[a]/ GS0102015*	Yes[32]/
Corn	TEP	Partially	GS0102031*[a]/ GS0102009* GS0102010* GS0102011*[b]/ GS0102022*	Yes[33]/

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Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
Oats	TEP	Partially	GS0102015* GS0102031*[a/]	Yes[32/]
Rice	TEP	Partially	GS0102018	Yes[34/]
Sorghum	TEP	Partially	GS0102023* GS0102009* GS0102031*[a/] 00095554* 00095502*	Yes[32/33/35/36/]
Wheat	TEP	Partially	GS0102024* GS0102031*[a/] GS0102002*	Yes[32/37/]
- Forage, Fodder, and Straw of Cereal Grain Group				
Barley, Green Fodder[38/] Straw	TEP	Partially	GS0102015* GS0102031*[a/]	Yes[39/]
Corn, Fodder Forage	TEP	Partially	GS0102022* GS0102011*[b/] GS0102010* GS0102009* GS0102031*[a/]	Yes[40]
Oat, Green Fodder[41/] Straw	TEP	Partially	GS0102015* GS0102031*[a/]	Yes[42/]

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Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
Rice, Straw	TEP	Yes	GS0102018	No
Sorghum, Fodder[40/] Forage	TEP	Partially	GS0102023* GS0102009* GS0102031*a/ 00095502* a/ 00095554*	Yes[43/]
Wheat, Green Fodder[41/] Straw	TEP	Partially	GS0102002* GS0102024* GS0102031*a/	Yes[44/]
- Non-Grass Animal Feeds (Forage, Fodder, Straw, and Hay) Group[45/]				
Alfalfa Alfalfa, hay	TEP	Partially	GS0102002* GS0102031*a/ 00095502* a/	Yes[46/]
Clover Clover, hay	TEP	Partially	GS0102025	No[46/]
Asparagus	TEP	Partially	GS0102013	Yes[47/]
Coffee Beans	TEP	Partially	GS0102010* GS0102008*	Yes[48/]
Cotton, forage Cottonseed	TEP	Partially	GS0102003* 00095622*	Yes[49/]

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Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
Hops	TEP	Yes	GS0102026[b/]	No
Peanuts[50/] Peanuts, hulls Peanuts, hay	TEP	Partially	GS0102018* GS0102011*[b/] GS0102031*[a/]	Yes[51/]
Pineapple Pineapple foliage	TEP	Partially	GS0102018	Yes[52/]
Sugarcane[53/]	TEP	Partially	GS0102010	Yes[54/]
Tobacco	TEP	Partially	00002477* 00095498*	Yes[55/]
- Crops Grown Solely for Seed				
Carrots	TEP	No	-	Yes[56/]
Garlic	TEP	No	-	Yes[56/]
Onions	TEP	No	-	Yes[56/]
Radishes	TEP	No	-	Yes[56/]
Turnips	TEP	No	-	Yes[56/]

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Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residues in Food-Producing Animals				
Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially	GS0102025* GS0102006* GS0102026*[b] GS0102027*[a] GS0102030*[a]	Yes[57]
— Post Processing Residue Studies	TGAI or plant metabolites	No	-	Reserved[58]

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GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

1/ Composition= TGAI= Technical grade of the active ingredient; PAIRA= Pure active ingredient, radiolabeled; TEP= Typical end-use product

2/ Data must be submitted no later than DEC 1986.

3/ Data delineating the quantification of each oxidative metabolite present in samples of crops representing each crop grouping must be submitted.

4/ Data delineating the quantification of oxidative metabolites present in meat, milk, poultry, and eggs must be submitted.

5/ a. Metabolism studies utilizing ruminants must be submitted. Animals must be dosed with [^{14}C] disulfoton at 12 ppm in the diet for 3 days. Milk must be sampled twice daily throughout the dosing period. Animals must be sacrificed within 24 hours of the final dose and residues characterized and quantified in milk, muscle, fat, kidney, and liver. The dose should include the following metabolites in a 1:5:2:10 ratio: disulfoton sulfoxide (II), disulfoton sulfone (III), disulfoton oxygen analog sulfoxide (V), and disulfoton oxygen analog sulfoxide (V), and disulfoton oxygen analog sulfone (VI). The ratio is based on plant metabolism studies. The animals should be sacrificed within 24 hours of the last dose. If ruminant metabolism is found to differ significantly from that of rats (based on previously-submitted rat metabolism studies), then non-ruminant (swine data) will be required.

b. Metabolism studies utilizing poultry must be submitted. Animals must be dosed with [^{14}C] disulfoton at 2.0 ppm in the diet for 3 days. Eggs must be sampled twice daily throughout the dosing period. Animals must be sacrificed within 24 hours of the final dose and residues characterized and quanitified in eggs, muscle, fat, gizzard, heart, liver and skin. The dose should include the same metabolites as those depicted for the ruminant study.

6/ A method must be provided which can be used without an oxidation step for the purpose of identifying and quantifying individual metabolites.

7/ Additional residue data must be submitted which reflects a single at-planting soil application (ground or aerial) followed by a single postemergent broadcast aerial application of a 15% G at 3 lb. a.i./A

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

rate. Residues must be determined 75 days after the second treatment. Tests must be conducted in Oregon and Washington.

8/ Data on residues in dehydrated sugar beet pulp, molasses, and refined sugar due to the processing of sugar beets having weathered, measurable residues must be submitted.

9/ A group tolerance is not appropriate at the present time because residue data are required for one additional member of this group (turnip leaves).

10/ A group tolerance is not appropriate at the present time because residue data are required for two additional members of this group (carrots and radishes).

11/ A group tolerance is not appropriate at the present time because residue data are required for one additional member of this group (celery).

12/ Additional data must be submitted reflecting residues in leaf and head lettuce (with and without wrapper leaves) grown in Arizona and California (including irrigated regions) a) 60 days after an at-plant banded soil application (spring-or summer-seeded) of a G or EC formulation at 1.2 oz. a.i./1000 feet of row (2.18 lb a.i./A with an 18 inch row spacing), and b) 60 days after a post-emergent banded soil application (fall-or winter-seeded) as a side-dress at thinning with one G and one EC formulation at 1.2 oz a.i,/1000 row feet (2.18 lb a.i./A with an 18-inch row spacing.)

13/ Additional data must be submitted reflecting residues in or on spinach grown in California (including irrigated regions) 42-50 days (normal harvest) after an at-plant banded soil application of a G or EC formulation at 0.6 oz a.i./1000 feet of row.

14/ A group tolerance is not appropriate at the present time because residue data are required for one additional member of this group (mustard greens).

15/ Additional residue data must be submitted using either a G or an EC formulation as a postemergence broadcast soil application at 0.92 oz. a.i./2500 square feet in the transplant bed followed by a single sidedress application (broccoli) at 1.125 oz. a.i./1000 feet of row to established plants in the field. For brussel sprouts, cabbage, and cauliflower, two sidedressings are necessary at above rate.

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GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

16/ Samples should be harvested 14 days after the sidedress treatment. Tests should be conducted in California (including irrigated regions).

17/ Samples should be harvested 30 days after the last sidedress treatment. Tests should be conducted in California (including irrigated regions).

18/ Samples should be harvested 42 days after the last sidedress treatment. Test should be conducted in California (11%), Florida (21%), New York (14%) and Texas (22%) (including irrigated regions); the percentages given for each state represent the contribution of each state to the total U.S. cabbage crop.

19/ Samples should be harvested 40 days after the last sidedress treatment. Tests should be conducted in California (including irrigated regions).

20/ A group tolerance is not appropriate at the present time because a) the established tolerances in or on dry beans, lima beans, snap beans, and peas are more than 5X greater than the established tolerance for soybeans; and b) the commodity definitions for lima beans as stated in 40 CFR 180.1 (J)(8) [beans and the pod] and for snap beans differ significantly from those for dry beans, peas, and soybeans.

21/ Residue data on soybean hulls, soapstock, and refined oil processed from soybeans having measurable weathered residues must be submitted. It may be necessary to use exaggerated rates to achieve measurable residues in the raw agricultural commodity. Should residues be found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

22/ A group tolerance is not appropriate at the present time because the established tolerance for bean and pea vines are more than 5X greater than the established tolerance for soybean forage.

23/ Additional residue data must be submitted for bean vine hay harvested 60 days after a single postemergent soil application (double banded sidedress on each side of row after plants are established) of a registered G or EC formulation at 1.9 oz a.i. (1000 feet of row). Tests must be conducted in California, Michigan, New York, and Oregon (major U.S. growing regions for dry, snap, and lima beans). Alternatively, a label restriction may be proposed which would prohibit feeding of bean vine hay to livestock.

24/ Additional residue data must be submitted for pea vine hay harvested 50 days after a simple postemergent soil application (banded sidedress after plants are established) of a registered G or EC formulation at 2.5 lb/A.

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GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

Tests must be conducted in Washington and Wisonsin since these states represent the majority of crop production area for green peas for processing. Alternatively, a label restriction may be proposed which would prohibit feeding of pea vine hay to livestock.

25/ Additional residue data are required for soybean hay harvested 75 to 125 days (depending on the prefeeding restriction proposed) after an atplanting application of one of the registered G formulations at 1.2 oz a.i./1000 feet of row. Tests must be conducted in Illinois, Minnesota, and Missouri since these states represent the major U.S. soybean production areas. Available data do indicate one of the following should be proposed for soybean forage a) a tolerance increase and a 75-day pregrazing and prefeeding restriction, or b) a 125-day pregrazing and prefeeding restriction. Should the registrant wish to propose a tolerance increase, we recommend a level of 2ppm, which would make the soybean forage and bean and vine tolerances compatible.

26/ While the existing tolerance on peppers is based on adequate residue data, this data was generated for a soil application. However, since there are no data available to support the state labels calling for foliar (EC) applications, residue data must be submitted from peppers harvested at intervals appropriate to the state labels after foliar treatment with an EC formulation at the maximum registered rate. The studies should take place in California.

27/ Additional residue data are required for tomatoes obtained from plants 30 days after the second of two postemergent soil applications, spaced 21 days apart, of the 6lb./gal/ EC and, in a separate test, a representative G formulation at 2.4 oz a.1./1000 feet of row. The plants used in the above trial should be grown in transplant beds that were treated postemergence at 2.75 oz a.i./2500 square feet with a representative G formulation. The field studies should take place in California.

28/ Additional residue data are required for tomatoes obtained 30 days after a single, postemergence soil application of the 6 lb/gal. EC and (in a separate test) a representative G formulation at 11 oz a.i./1000 feet of row (72-inch row spacing). The plants used in the above trial should be raised in transplant beds treated postemergent at 2.75 oz a.i./2500 square feet with a representative G formulation. The field studies should take place in an alkaline soil in Florida.

29/ Residue data must be submitted for puree, catsup, juice, wet and dry pomace obtained by processing tomatoes having weathered residues at or above the tolerance. This may require that the tomatoes be treated at exaggerated rates.

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

30/ A group tolerance is not appropriate at the present time because residue data are required for two additional members of this group (almond and English walnut).

31/ No additional data are required; however the existing tolerance should be decreased from 0.75 ppm to 0.1 ppm in order to correspond with expected residues at the highest label rate (3 lb a.i./A)(EC); and also to achieve compatibility with Codex MRL.

32/ Residue data are required from the milled products of wheat grain, obtained by processing wheat grain samples containing measurable weathered residues. This may require that wheat samples be treated at exaggerated rates. This data will be translated to barley, oats, and sorghum to totally or partially fulfill the same requirements for these commodities.

33/ Residue data are required from representative processed products of field corn, including crude oil, refined oil, and milled products, and sweet corn (cannery waste) after processing corn bearing measurable weathered residues. This may require that corn samples be treated at exaggerated rates. This data will be translated to sorghum to partially fulfill the same requirement for this commodity.

34/ Residue data are required from rice and its milling products, including polished rice, hulls, and other milled products, obtained from rice bearing measurable weathered residues. This may require that rice be treated at exaggerated rates.

35/ Residue data are required from sorghum grain harvested 7 days after the second of two foliar applications, spaced three days apart, at 1 lb. a.i./A. Separate tests of aerial and ground applications should be done in Texas and Oklahoma.

36/ Additionally, information must be submitted to indicate the rate of application in oz a.i./1000 feet of row for all soil treatments. Current label rates given as 1 lb. a.i./A may correspond to as low as 0.43 oz a.i./1000 feet of row, if a narrow (14-inch) row spacing was used, and thus the maximum or near maximum rate would not be represented by much of the data currently in the Agency files.

37/ Residue data are required from winter wheat grain harvested 30 days after the last of the following treatments: an at-planting, fall application of the 15% G at 1 lb a.i./A followed by two foliar treatments with the 6 lb./gal. EC at 0.75 lb. a.i./A at 30 day intervals in the fall, followed in the spring by two identical foliar

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

treatments starting 90 days before expected harvest. The studies should be done in Texas, Nebraska, California, Montana, Tennessee, and New York which represent the major winter wheat production areas, as well as the various climatic regions of the U.S. Foliar treatments must be applied in separate tests using aerial and ground equipment.

38/ A tolerance for barley hay must be proposed, based upon the data requested in 39/. Also the commodity definition "green fodder" should be changed to "forage".

39/ Additional residue data must be submitted from barley forage and hay cut 30 days after the second treatment of each of the following two treatment regimes: a) a pre-emergence soil application and a post-emergence foliar application, following as soon as is normally practiced, of the 6 lb./gal EC at 1 lb. a.i./A; b) two ground-applied, foliar treatments spaced at a practical interval, of the 6 lb./gal EC at 1 lb. a.i./A. In addition residue data from straw cut 60 days after the former treatment regime (a) should be submitted. The studies should be conducted in California, Montana, North Dakota, and Washington.

40/ Additional residue data must be submitted and tolerances proposed for both corn and sorghum silage. Such data should be derived for corn silage produced by ensiling corn forage bearing weathered residues at or near the 5 ppm tolerance. Exaggerated rates or early harvesting may be required to obtain such forage. If not concentration of residues takes place, the corn silage tolerances should be proposed at 5 ppm; if concentration does occur, an appropriately higher tolerance should be recommended. These data will also be used to propose a tolerance for disulfoton residues in or on sorghum silage.

41/ The commodity definition "green fodder" should be changed to "forage".

42/ A tolerance must be proposed for oat hay based upon data requested for wheat hay in 44/.

43/ Additional residue data must be submitted for sorghum fodder subject to an at-plant application with a G formulation at 1.2 oz a.i./1000 row feet followed by a postemergence sidedress treatment with an EC at 0.5 lb. a.i./A followed by a postemergence sidedress treatment with an EC at 0.5 lb a.i./A followed by three aerially-applied foliar treatments with an EC at 1 lb a.i./A. Fodder should be prepared for sampling 34 days after the final treatment. Studies must be conducted in Oklahoma and Texas. Residue data must also be submitted from sorghum fodder and forage harvested 28 days after the second of two foliar applications of an EC, spaced 3 days apart, at 0.5 lb. a.i./A. Tests should take place in Texas.

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

44/ Additional residue data must be submitted and tolerances proposed for both oat and wheat hay. Such data should be derived from wheat forage, hay, and straw taken 30 days after the last of the following treatments: an at-planting, fall application with a G formulation at 1 lb. a.i./A, a broadcast application of the 0.75% G at 0.75 lb. a.i./A made when the crop is established, followed by two foliar treatments with the 6 lb/gal. EC at 0.75 lb a.i./A at 30 day intervals, followed in the spring by two identical foliar treatments starting 90 days before expected harvest. Foliar applications should be made with aerial and ground equipment and should take place in Texas, Nebraska, California, Montana, and Tennessee, which represent the major wheat producing areas registered as use sites.

45/ A group tolerance is not appropriate at the present time because a 7-day preharvest interval (PHI) has been established for clover, whereas no PHI exists for alfalfa. Since both crops are commonly planted in mixtures, the disparity between PHI's is unrealistic and must be resolved.

46/ Additional data are required which reflect residues in or on alfalfa (fresh) and alfalfa hay samples collected at 0, 7, and 14 days after the last of four broadcast applications (one at-planting and three prior to growth from established stubble) made during one growing season. Tests should reflect use of the 15% G or the 6 lb./gal. EC formulation at 1 lb a.i./A application in California (8%), Nebraska (6%) and Wisconsin (11%); the percent contribution to annual U.S. alfalfa production is given in parenthesis. Additional data are also being required which reflects residues in or on alfalfa hay and seed harvested 14 days after the last of four aerial and ground foliar applications with the 6 or 8 lb./gal. EC formulation at 1 lb. a.i./A. Tests should be conducted at the sites detailed above. Upon submission of data pertaining to alfalfa seed, a tolerance for disulfoton residues in or on alfalfa seed must be proposed, if necessary. Finally, a processing study is required to determine residues in meal processed from field-treated hay containing detectable, weathered residues; if residues are found to concentrate in meal, a feed additive tolerance must be proposed. The above data on alfalfa will be translated to clover.

Note: Until the above data is submitted a grazing restriction must be placed on the appropriate product labels for alfalfa hay, in addition to the existing restriction against feeding and foraging of cut green alfalfa grown for seed production.

47/ Additional residue data must be submitted for asparagus (fresh spears) harvested 4 months after the last of three foliar applications made at greater than 14-day intervals with the 8 lb./gal. EC formulation at 1 lb. a.i./A in the states of California and Washington. Applications must be made using ground and aerial equipment.

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

48/ Additional residue data must be submitted for coffee beans bearing measurable weathered residues; it may be necessary to use exaggerated application rates to obtain detectable residues in the green coffee beans. If residues are found to concentrate in instant coffee, a food additive tolerance must be proposed.

49/ Additional residue data must be submitted for cottonseed and forage after the following consecutive treatments: (a) seed treatment with the 9.14 lb./gal. RTU formulation at 8 oz. a.i./100 lb of seed; (b) a preplant banded soil application of a registered EC formulation at 1.2 oz a.i./1,000 feet of row; (c) an at-plant band soil application of a registered G and EC formulation at 1.0 oz a.i./1,000 feet of row; and (d) two postemergent soil applications (made 21 days apart) of a registered G and EC formulation at 1.2 and 2.4 oz a.i./1,000 feet of row (G formulation at 2.4 oz rate on irrigated cotton only). Seed samples should be collected 28 days after the last postemergent treatment at 1.2 oz. a.i./1,000 feet of row and 90 days after the last postemergent treatment at 2.4 oz./a.i./1,000 feet of row. Forage samples should be collected in Arizona, California, Mississippi, and Texas which together account for 80% of U.S. cotton production.

Also data must be reflecting residues in or on cottonseed and forage after seed treatment with the 9.14 lb/gal. RTU formulation at 8 oz. a.i./100 lb. of seed followed by three foliar spray applications made prior to bloom of the 6 or 8 lb/gal. EC formulation at 9 oz...a.i./A, foliar application should be made using both aerial and ground equipment. Cottonseed data are required only for aerially-applied treatments. Forage samples should be collected at weekly intervals throughout the growing season. Tests should be conducted in the same states noted above.

Finally data must be submitted reflecting residues in meal, hulls, soapstock, and crude and refined oil processed from cottonseed bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, then appropriate food/feed additive tolerances must be proposed.

The above required data for cottonseed forage must be accompanied by a tolerance proposal. Alternatively, grazing and feeding restrictions may be proposed.

50/ A tolerance msut be proposed for peanut vines based upon data requested in 51/ below.

51/ Additional residue data must be submitted for the processed commodities peanut meal, crude oil, soapstock, and refined oil. The processed commodities must be derived from peanuts containing detectable, field weathered residues. Additionally residue data must be submitted for peanuts, peanut hulls, hay and vines reflecting one preplant, broad-

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

cast, soil-incorporated application of 6-8 lb./gal. EC formulation at 6 lb. a.i./A followed by two soil applications of a G or EC formulation, both early postemergence and at-pegging at 2.25 oz. a.i./1000 feet of row (at least 2 lb. a.i./A).

52/ Additional residue data must be submitted in which residues are measured in or on pineapple forage (foliage) 60 days after the last of two broadcast applications made during the same crop season with one of the G formulations at 2.5 lb. a.i./A; the final application must be applied by leaf base feeding. Tests should be conducted in Hawaii. Also required is a determination of residues in juice and bran processed from disulfoton - treated pineapple, bearing detectable, weathered residues.

53/ Since sugarcane forage is used for animal feed, appropriate residue data (noted below), a tolerance proposal, and a pregrazing interval proposal are required; alternatively, a feeding and grazing restriction may be proposed.

54/ Also additional data must be submitted reflecting residues in or on sugarcane and sugarcane forage following four weekly foliar applications (both aerial- and ground-applied) of one of the registerd EC formulations at 9 oz. a.i./A. Sugarcane should be harvested 28 days after the last treatment. Forage should be sampled throughout the treatment period and at weekly interval thereafter up to 28 days. Tests should be conducted in Puerto Rico and Florida.

Finally data reflecting residues in or on molasses, refined sugar, and bagasses processed from sugarcane bearing measurable weathered residues must be submitted. It may be necessary to use exaggerated application rates to achieve detectable residues in the raw agricultural commodity. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerance must be proposed.

55/ Additional data must be submitted which reflects residues of disulfoton and its cholinesterase-inhibiting metabolites in or on green freshly-harvested tobacco treated with a postemergent broadcast soil application (in the transplant bed) of one the registered G formulations at 3.75 oz a.i./2,5000 square feet followed by a preplant incorporated soil application (in the field) of one of the G formulations at 6 oz. a.i./1,000 feet of row and, in separate tests, one of the registered EC formulations at 4 lb. a.i./A.

If residues of >0.1 ppm are detected in the green, freshly harvested tobacco, then pyrolysis products derived from disulfoton and its cholinesterase-inhibiting metabolites, and/or formulation impurities must be characterized and quantified.

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.125 Residue Chemistry (continued)

56/ At the time these uses were registered, residue data was not required. Presently these uses are considered as feed uses, unless supportive residue data are available to indicate no detectable residues occur in the plants as a result of the maximum registered use rate. Since such data is not presently available, it must be submitted. If the data indicate residues do occur in these commodities, appropriate tolerances must be requested.

57/ The metabolism of disulfoton in animals is not adequately understood. Additional data is being requested (in 4/) to identify and quantify metabolites. Should metabolites of concern differ from those currently sought, additional data will be required. The available data indicate the necessity of proposing tolerances for poultry at 0.01 ppm and eggs at 0.001 ppm (limits for sensitivity of available methods)

58/ The requirement for these data will be reserved, pending receipt and evaluation of the appropriate residue studies noted above.

*All references must be cited

a) Studies submitted by Chemagro Ag. Div., Mobay Corp. These data may be compensable.
b) Studies submitted by Chemagro Corp. These data may be compensable.

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section (c)(2)(B)?3/ (See asterisks)
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,F,G	No	-	Yes*
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,C,G	No	-	Yes*
161-3 - On soil	TGAI or PAIRA	A,G	No		Yes*
161-4 - In Air	TGAI or PAIRA	A	No	-	Yes***
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G	No		Yes**
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes**
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,G	No	-	Yes**
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No	-	Yes***
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,G	Partially	00068214a/	Yes4/*

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section (c)(2)(B)?[3/] (See asterisks)
§158.130 Environmental Fate					
163-2 - Volatility (Lab)	TEP	A,G	No	-	Yes***
163-3 - Volatility (Field)	TEP	A,G	No	-	Yes***
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	Partially[5/]	00068096[b/]	Yes[6/]**
164-2 - Aquatic (Sediment)	TEP	C	No	-	Yes***
164-3 - Forestry	TEP	G	No	-	Yes**
164-4 - Combination and Tank Mixes	-	-	-	-	Yes***
164-5 - Soil, Long-term	TEP	A,C	No	-	Yes***
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No	-	Yes***
165-2 - Rotational Crops (Field)	TEP	A	No	-	Yes***
165-3 - Irrigated Crops	TEP	C	No	-	Yes***

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section (c)(2)(B)?3/ (See asterisks)
§158.130 Environmental Fate (continued)					
165-4 - In Fish	TGAI or PAIRA	A,C	No	-	Yes
165-5 - In Aquatic Non-Target Organisms	TEP	C,G	No	-	Yes

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than *June 1985, **December 1986, ***December 1987.

4/ Require one study of absorption/desorption on aquatic sediment, and mobility data for disulfoton on sandy loam.

5/ Data identifies degradates sulfone and sulfoxide, but lacks information on decline of disulfoton and/or degradates.

6/ Require test on representative domestic soil and at highest recommended label rates.

a) Studies submitted by Mobay Chemical Corporation. These data may be compensable.

b) Studies submitted by ICI America, Inc. These data may be compensable.

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section (c)(2)(B)?[3/] (See asterisks)
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral - Rat	TGAI	A,B,C,D,E F,G,H	Yes	GS0102300[a/]	No
81-2 - Dermal	TGAI	A,B,C,D,E, F,G,H	Yes	GS0102300[a/]	No
81-3 - Inhalation - Rat	TGAI	A,B,C,D,E F,G,H	No	-	Yes*
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,C,D,E F,G,H	No	-	Yes*
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-Rodent	TGAI	A,C,E	No	-	Yes[4/]*
82-2 - 21-Day Dermal	TGAI	A,E,F,G	No	-	Yes[5/]**
82-3 - 90-Day Dermal	TGAI	A,E,F,G	No	-	No[6/]

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section (c)(2)(B)?[3] (See asterisks)
§158.135 Toxicology (continued)					
SUBCHRONIC TESTING (continued)					
82-4 - 90-Day Inhalation - Rat	TGAI	A,E,F,G	No	-	Yes[7]/**
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	A,E,F,G	No	-	Yes[8]/**
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,C,E	Partially	00073348[a]	Yes[9]/***
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,C,E	Partially	GS0102301[a]	Yes[9]/****
83-3 - Teratogenicity - 2 species	TGAI	A,B,C,E F,G,H,I	Partially	GS0102302[a]	Yes[10]/****
83-4 - Reproduction, 2-generation	TGAI	A,B,C,D E,F,G	No	-	Yes****
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B,C,E	Partially	GS0102303	Yes[11]/****

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section (c)(2)(B)?[3]/ (See asterisks)
§158.135 Toxicology (continued)					
		F,G,I			
MUTAGENICITY TESTING (continued)					
84-2 - Chromosomal Aberration	TGAI	A,B,C,E, F,G,I	No	-	Yes[12]/****
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,C,E, F,G,I	Partially	00028625[b]/	Yes[13]/****
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,C,F,I	Partially	00083251 GS0102006[a]/	Yes[14]/**
85-2 - Domestic Animal Safety	Choice	A,B	Yes	00013487[c]/	No
—— - Dermal Absorption	TEP	A,B,G	No	-	Yes[15]/*
—— - Product Integrity Studies	TEP (Granular)	A,B,C,D, E,F,G,H,I	No	-	Yes[16]/*

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.135 Toxicology (continued)

1/ Composition: PAI = Pure active ingredient: PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C-Aquatic, Food Crop; D= Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than *June 1985, **December 1985, ***January 1985, ****December 1987.

4/ Using oxidation matabolites of disulfoton.

5/ Only if worker exposure analysis indicates potential hazard of repeated exposure.

6/ The 21 day dermal study would be sufficient to assess the possible dermal exposure associated with the current pesticidal use of disulfoton.

7/ Only if worker exposure analysis indicates potential hazard of repeated exposure, and if product integrity studies indicate that respirable dust is generated during shipping and handling (see data gaps).

8/ Contingent upon the outcome of the acute delayed neurotoxicity study.

9/ Testing required in the rat.

10/ Testing required in another species (other than the rat).

11/ In vitro mammalian cell; LS178 (TK), CHO (HGPRT), or V79 (HGPRT).

12/ Sister chromatid exchange in CHO cells or human lymphocytes and dominant lethal.

13/ Contingent upon the outcome of 7 and 8 above.

14/ An adequate study is required to delineate the pharmacokinetic and pharmacodynamic aspect. Preferred test organism is the rat.

15/ In order to estimate toxicity which may result from dermal exposure to the chemical or its major metabolites, an estimate of the rate of dermal penetration of these moieties must be established. Dermal uptake kinetics and excretion kinetics studies must be provided to estimate body dose at any point in time after exposure. Such studies are necessary for the risk assessment to those occupationally or accidentally exposed dermally.

16/ A proposed protocol is to be submitted and approved by the Agency prior to initiating these studies.

a) Studies submitted by Mobay Chemical Corp. These data may be compensable.
b) Studies submitted by FMC Corp. These data may be compensable.
c) Studies submitted by Chemagro Corp. These data may be compensable.

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B,C,F,G	No	-	Yes[4][5]
132-1 - Soil Dissipation	TEP	A,B,C,F,G	No	-	Yes[4][5]
133-3 - Dermal Exposure	TEP	A,B,C,F,G	No	-	Yes[4][5]
133-4 - Inhalation Exposure	TEP	A,B,C,F,G	No	-	Yes[4][5]

1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aquatic, Non-Food: E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than DEC 1987.

4/ An interim 24 hour reentry interval is imposed for these use patterns pending the receipt and evaluation of reentry data. Workers may reenter within that interval if protective clothing is worn.

5/ Analysis of residues should include both qualitative and quantitative assays for oxidative metabolites.

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.142 Aerial Spray Drift					
201.1 - Droplet Size Spectrum Testing	TEP	A,B,C,D,G	No	-	Yes
202.1 - Drift Field Evaluation	TEP	A,B,C,D,G	No	-	Yes

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aquatic, Non-Food: E=Greenhouse, Food Crop; F=Greenhouse, Non-Feed; G=Forestry, H=Domestic Outdoor, I=Indoor.
3/ Data must be submitted no later than DEC 1986.

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral	TGAI	A,B,G,H	Yes	00095655*a/ GS0102700* 05008363**	Reserved[4]/
71-2 - Avian Dietary a-Waterfowl	TGAI	A,B,G,H	Yes	00094233*a/ 00058746*	Reserved[4]/
b.Upland game	TGAI	A,B,G,H	Yes	00094233*a/	Reserved[4]/
71-3 - Wild Mammal Toxicity	TGAI	A,G	No	-	Reserved[4]/
71-4 - Avian Reproduction	TGAI	A,B,G	No	-	Reserved[5]/
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A	Partially	00095658**a/ 00095657**a/	Yes[6]/
AQUATIC ORGANISM TESTING					
72-1 - Acute Freshwater Fish a. Warmwater	TGAI	A,B,G,H	Yes	00068268**a/ 00003503**	No
b. Coldwater	TGAI	A,B,G,H	Yes	00068268**a/ 00003503**	No

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
§158.145 Wildlife and Aquatic Organisms (continued)					
AQUATIC ORGANISM TESTING (continued)					
72-2 - Acute Freshwater Invertebrates	TGAI	A,B,G,H	Partially[7/]	00003503**	Yes
72-3 - Acute Estuarine and Marine Organisms					
a. Shrimp	TGAI	A,B	No		Yes[8/]
b. Marine fish	TGAI	A,B	No		Yes[8/]
c. Oyster	TGAI	A,B	No		Yes[8/]
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B	No	-	Reserved[4/]
72-5 - Fish Life-Cycle	TGAI	A,B	No	-	Reserved[4/6/9/]
72-6 - Aquatic Organism Accumulation	TGAI	A,B	No	-	Reserved[4/]
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B	No	-	Reserved[4/]

TABLE A
GENERIC DATA REQUIREMENTS FOR DISULFOTON

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI - Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor I=Indoor.

3/ Data must be submitted no later than JUN 1986.

4/ Reserved pending results of metabolism data. Toxicity studies on metabolites may be required.

5/ Reserved pending indication of Environmental Fate information.

6/ Field studies are required due to the toxicity of the chemical in relation to expected environmental concentrations. At this time three field monitoring studies are required: One for the use of the 15% granular product on a crop with higher use rates, one for the use of the emulsifiable concentrate band treatment on a crop with a higher use rates and one for the broadcast foliar application. Depending on the results of studies, further testing on additional crops may be necessary.

7/ A more sensitive life stage must be tested.

8/ Disulfoton has LC_{50} values below 1 ppm for aquatic invertebrate and fish. Several crops are grown in excess of 300,000 acres in coastal counties. The following disulfoton uses meet this requirement: corn, soybean, sorghum and cotton.

9/ Reserved pending results of test 72-4.

* Study on its own fulfills Guideline Requirement

** Study must be combined with other studies to fulfill Guideline Requirement.

a) Studies submitted by Mobay Chemical Corp. These data may be compensable.

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact	TGAI	A,B	Yes	00066220a/ 05001991 05004151	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	No		Yes
141-4 - Honey bee subacute feeding study	[Reserved]4/				
141-5 - Field testing for pollinators	[Reserved]4/				
142-1 - Acute toxicity to aquatic insects	[Reserved]5/				
142-2 - Aquatic insect life-cycle study	[Reserved]5/				
142-3 - Simulated or actual field testing for aquatic insects	[Reserved]5/				

TABLE A

GENERIC DATA REQUIREMENTS FOR DISULFOTON

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
143-1 thru 143-3 - NONTARGET INSECT TESTING PREDATORS AND PARASITES	[Reserved][5/]				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than JUN 1980.
4/ Reserved pending development of test method.
5/ Reserved pending Agency decision as to whether data requirement should be established.

a) Studies submitted by Penick Corp. These data may be compensable.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DISULFOTON

Data Requirement	Test Substance[1]/	Guidelines Status[2]/	Are Data Required[3]/		Footnote Number
			Yes	No	
§158.120 - Product Chemistry					
Product Identity:					
61-1 - Identity of Ingredients	MP	R	☒	☐	
61-2 - Statement of Composition	MP	R	☒	☐	
61-3 - Discussion of Formation of Ingredients	MP	R	☒	☐	
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	R	☒	☐	
62-2 - Certification of Limits	MP	R	☒	☐	
62-3 - Analytical Methods for Enforcement of Limits	MP	R	☒	☐	
Physical and Chemical Characteristics					
63-2 - Color	MP	R	☒	☐	
63-3 - Physical State	MP	R	☒	☐	
63-4 - Odor	MP	R	☒	☐	

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DISULFOTON

Guideline Citation and Name of Test Data Requirement	Test Substance[1/]	Guidelines Status[2/]	Are Data Required[3/]		Footnote Number
			Yes	No	
§158.120 - Product Chemistry (cont'd)					
Physical and Chemical Characteristics (Continued)					
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	☒	☐	
63-12 - pH	MP	R	☒	☐	
63-14 - Oxidizing or Reducing Action	MP	CR	☒	☐	
63-15 - Flammability	MP	CR	☒	☐	
63-16 - Explodability	MP	R	☒	☐	
63-17 - Storage Stability	MP	R	☒	☐	
63-18 - Viscosity	MP	CR	☒	☐	
63-19 - Miscibility	MP	CR	☒	☐	
63-20 - Corrosion Characteristics	MP	R	☒	☐	
Other Requirements:					
64- 1 - Submittal of samples	PAI	CR	☐	☒	

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DISULFOTON

§158.120 - Product Chemistry (cont'd)

1/ Test Substance: MP= Manufacturing-use Product; PAI= Pure active ingredient; Choice= Choice of several test substances on a case-by-case basis.

2/ Guideline Status: R= Required; CR= Conditionally required

3/ Data must be submitted by JUN 1985

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DISULFOTON

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)? [1/]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral	Granular containing 2% ai	No	-	Yes
	Granular containing 2.2% ai	No	-	Yes
	Granular containing 5% ai	No	-	Yes
	Emulsifiable conc. cont. 68% ai	No	-	Yes
81-2 - Dermal	Granular containing 2% ai	No	-	Yes
	Granular containing 2.2% ai	No	-	Yes
	Granular containing 5% ai	No	-	Yes
	Emulsifiable conc. cont. 68% ai	No	-	Yes
81-3 - Inhalation	Granular containing 2% ai	No	-	Yes
	Granular containing 2.2% ai	No	-	Yes
	Granular containing 5% ai	No	-	Yes
	Emulsifiable conc. cont. 68% ai	No	-	Yes
81-4 - Primary Eye Irritation	Granular containing 2% ai	No	-	Yes[2/]
	Granular containing 2.2% ai	No	-	Yes[2/]
	Granular containing 5% ai	No	-	Yes[2/]
	Emulsifiable conc. cont. 68% ai	No	-	Yes[2/]
81-5 - Primary Dermal Irritation	Granular containing 2% ai	No	-	Yes[2/]
	Granular containing 2.2% ai	No	-	Yes[2/]
	Granular containing 5% ai	No	-	Yes[2/]
	Emulsifiable conc. cont. 68% ai	No	-	Yes[2/]
81-6 - Dermal Sensitization	Granular containing 2% ai	No	-	No[3/]
	Granular containing 2.2% ai	No	-	No[3/]
	Granular containing 5% ai	No	-	No[3/]
	Emulsifiable conc. cont. 68% ai	No	-	No[3/]

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DISULFOTON

§158.135 Toxicology
(continued)

1/ Data must be submitted no later than JUN 1985.

2/ Testing is contingent upon toxicity category as determined by the acute oral, dermal and inhalation toxicity. Chemicals in toxicity category I are not to be tested for their eye or dermal irritating potential.

3/ The chemical structure of disulfoton does not indicate a possible dermal sensitization potential. The inerts used in the formulations do not seem to have skin sensitization potential.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING DISULFOTON

Data Requirement	Composition1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity Rat	EP	No	-	Yes3/
81-2 - Acute Dermal Toxicity	EP	No	-	Yes3/
81-3 - Acute Inhalation Toxicity - Rat	EP	No	-	Yes3/

1/ Composition: EP = end-use product.

2/ Data must be submitted no later than June 1985.

3/ (a) For new end-use granular products greater than 2.0% disulfoton. Either these data must be submitted and evaluated prior to registration or the products must be labeled for restricted use.

(b) For currently registered end-use granular products containing greater than 2.0% disulfoton. These products must be labeled for restricted use pending receipt and evaluation of these data.

(c) For new currently registered end-use granular products containing 2.0% disulfoton or less. Data must be submitted in order to evaluate the appropriate toxicity category and to consider the appropriateness of classifying these products for restricted use.

IV. SUBMISSION OF REVISED LABELING INFORMATION

Note: This section applies to all products containing disulfoton.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section and/or Section I, EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is require on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses to be restricted, based either on a previous classification determination made through the optional procedures of 40 CFR 162.30 or based on data already available to the Agency, or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you wish to propose that your product should not be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

A. Classification Labeling Requirements

1. All Uses Restricted - Pesticide products bearing directions for use for formulations or uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

a. The statement "RESTRICTED USE PESTICIDE," must appear at the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR 162.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some But Not all Uses Restricted - If the Regulatory Position and Rationale states that some uses are classified for restricted use and some uses are unclassified, several courses of action are available:

a. You may label the product for restricted use. If you do so, you may include those uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one containing only unrestricted uses, and the other restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after September 1, 1985, without bearing the restricted use classification. All products still in channels of trade after September 1, 1986, must be labeled for restricted use.

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

George T. LaRocca
Product Manager (15)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-2400

For each product for which continued registration is desired:

A. For Manufacturing Products (MP) containing only disulfoton as an active ingredient.

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

   d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section II (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

   e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager.

B. For Manufacturing Use Products containing Disulfoton in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notifiy the Product Manager.

C. For End Use products containing disulfoton alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA For 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data. (Refer to Table C)

   d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section II (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. For those end use product registrations that are not eligible for the formulations exemption [FIFRA sec. 3(c)(2)(D)], submit all generic data within the time set forth in Table A.

Appendix II-1

Guide to Use of This Bibliography

1. **CONTENT OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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APPENDIX II-2
OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the *Registration Guidelines* or the *Protocols* contained in the *Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme*, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

Reproduced from best available copy.

REGISTRANT'S AUTHORIZED REPRESENTATIVE

SIGNATURE

DATE

EPA Form 8580-1 (10-82)

APPENDIX II-2

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

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NAME OF OTHER REGISTRANT

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☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

Appendix III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________ Guidance Document for________________________

Date________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				

63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

APPENDIX IV-2 (continued)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Appendix IV-5
(continued)

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4-Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

Appendix IV-5
(continued)

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

Appendix IV-5
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2.4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

Appendix IV-5
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

B26A/10

Appendix IV-5
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silver
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene